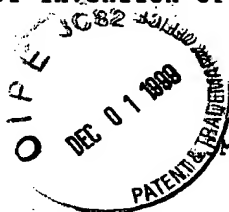


Applicant or Patentee: John O'Connor, et al. Attorney's 3  
Serial or Patent No.: Not Yet Known Docket No 54205-B/JPW  
Filed or Issued: Herewith /JSG  
Title of Invention or Patent: METHODS FOR PREDICTING PREGNANCY OUTCOME IN A  
SUBJECT BY HCG ASSAY



VERIFIED STATEMENT (DECLARATION) CLAIMING  
SMALL ENTITY STATUS UNDER 37 C.F.R. §1.9(f)  
AND §1.27(d) - NONPROFIT ORGANIZATION

I hereby declare that I am an official empowered to act on behalf of the nonprofit organization identified below:

Name of Organization: The Trustees of Columbia University in the City of New York  
Address of Organization: 110 Low Memorial Library, West 116th & Broadway,  
New York, New York 10027

TYPE OF ORGANIZATION:

☒ UNIVERSITY OR OTHER INSTITUTION OF HIGHER EDUCATION  
☐ TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE 26 U.S.C. §§501(a) and 501(c)(3)  
☐ NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA  
NAME OF STATE: \_\_\_\_\_  
CITATION OF STATUTE: \_\_\_\_\_  
☐ WOULD QUALIFY AS TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE 26 U.S.C. §§501(a) and 501(c)(3) IF LOCATED IN THE UNITED STATES OF AMERICA  
☐ WOULD QUALIFY AS NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA IF LOCATED IN THE UNITED STATES OF AMERICA  
NAME OF STATE: \_\_\_\_\_  
CITATION OF STATUTE: \_\_\_\_\_

I hereby declare that the nonprofit organization identified above qualifies as a nonprofit organization as defined in 37 C.F.R. §1.9(e)\* for purposes of paying reduced fees under 35 U.S.C. §41(a) and 41(b), with regard to the invention entitled METHODS FOR PREDICTING PREGNANCY OUTCOME IN A SUBJECT BY HCG ASSAY

by inventor(s) John O'Connor, et al.

described in:

☒ the specification filed herewith  
☐ application serial no. \_\_\_\_\_ filed \_\_\_\_\_  
☐ patent no. \_\_\_\_\_ issued \_\_\_\_\_

I hereby declare that rights under contract or law have been conveyed to and remain with the nonprofit organization with regard to the above identified invention.

If the rights held by the nonprofit organization are not exclusive each individual, concern, or organization known to have rights to the invention is listed below<sup>a</sup> and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 C.F.R. §1.9(d)\* or a nonprofit organization under 37 C.F.R. §1.9(e)\*

<sup>a</sup>NOTE: Separate verified statements are required from each person, concern, or organization having rights to the invention averring to their status as small entities. 37 C.F.R. §1.27.

Name: N/A

Address: \_\_\_\_\_  
\_\_\_\_\_  
☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

\*See Reverse

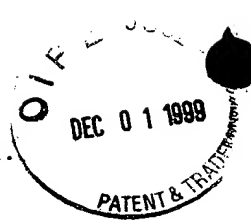
Small Entity, Nonprofit:

Page -1-

Applicants: John O'Connor, et al.

U.S. Serial No.: Not Yet Known

Filed: Herewith



I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. 37 C.F.R. §1.28(b)\*.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of Person Signing: Mr. Jack M. Granowitz

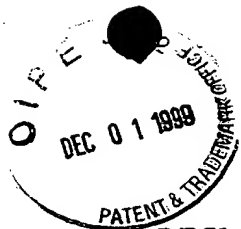
Title In Organization: Executive Director, Columbia Innovation Enterprise

Address: Amsterdam & 120th Street - Suite 363 New York, New York 10027

Signature: *Jack M. Granowitz*

Date Of Signature: May 14, 1999

\*See Reverse

**DECLARATION AND POWER OF ATTORNEY**

*As a below-named inventor, I hereby declare that:*

*My residence, post office address, and citizenship are as stated below next to my name.*

*I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:*

**METHODS FOR PREDICTING PREGNANCY OUTCOME IN A SUBJECT BY hcG ASSAY**

*the specification of which:  
(check one)*

\_\_\_\_\_ *is attached hereto.*

☒ *was filed on* May 13, 1999 *as*

*Application Serial No.* 09/311,428

*and was amended* \_\_\_\_\_  
*(if applicable)*

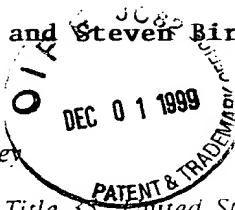
*I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.*

*I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.*

*I hereby claim foreign priority benefits under Title 35, United States Code, Section 119 (a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International Application which designated at least one country other than the United States, listed below. I have also identified below any foreign application for patent or inventor's certificate, or PCT International Application having a filing date before that of the earliest application from which priority is claimed:*

<i>Prior Foreign Application(s)</i>			<i>Priority Claimed</i>	
<u>Number</u>	<u>Country</u>	<u>Filing Date</u>	<u>Yes</u>	<u>No</u>
PCT/US99/02289	PCT	February 3, 1999	<input checked="" type="checkbox"/>	<input type="checkbox"/>
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
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_____	_____	_____	_____	_____
_____	_____	_____	_____	_____

Applicants: John O'Connor and Steven Birken  
Serial No.: 09/311,428  
Filed: May 13, 1999



Declaration and Power of Attorney

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I hereby claim the benefit under Title 35, United States Code, Section 119(e) of any United States provisional application(s) listed below:

<u>Provisional Application No.</u>	<u>Filing Date</u>	<u>Status</u>
<u>N/A</u>		

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States Application(s), or Section 365(c) of any PCT International Application(s) designating the United States listed below. Insofar as this application discloses and claims subject matter in addition to that disclosed in any such prior Application in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56 which became available between the filing date(s) of such prior Application(s) and the national or PCT international filing date of this application:

<u>Application Serial No.</u>	<u>Filing Date</u>	<u>Status</u>
<u>09/017,976</u>	<u>February 3, 1999</u>	<u>Pending</u>
<u>PCT/US99/02289</u>	<u>February 3, 1999</u>	<u>Pending</u>

And I hereby appoint

John P. White (Reg. No. 28,678); Christopher C. Dunham (Reg. No. 22,031); Norman H. Zivin (Reg. No. 25,385); Jay H. Maioli (Reg. No. 27,213); William E. Pelton (Reg. No. 25,702); Robert D. Katz (Reg. No. 30,141); Peter J. Phillips (Reg. No. 29,691); Wendy E. Miller (Reg. No. 35,615); Richard S. Milner (Reg. No. 33,970); Albert Wai-Kit Chan (Reg. No. 36,479); Robert T. Maldonado (Reg. No. 38,232); Paul Teng (Reg. No. 40,837); Gary J. Gershik (Reg. No. 39,992); Richard F. Jaworski (Reg. No. 33,515); Elizabeth M. Wieckowski (Reg. No. 42,226); and Pedro C. Fernandez (Reg. No. 41,741)

and each of them, all c/o Cooper & Dunham LLP, 1185 Avenue of the Americas, New York, New York 10036, my attorneys, each with full power of substitution and revocation, to prosecute this application, to make alterations and amendments therein, to receive the patent, to transact all business in the Patent and Trademark Office connected therewith and to file any International Applications which are based thereon under the provisions of the Patent Cooperation Treaty.

Applicants: John O'Connor and Steven Birken  
Serial No.: 09/311,428  
Filed: May 13, 1999



Declaration and Power of Attorney

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Please address all communications, and ~~fax~~ all telephone calls, regarding this application to:

John P. White

Reg. No. 28,678

Cooper & Dunham LLP  
1185 Avenue of the Americas  
New York, New York 10036  
Tel. (212) 278-0400

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or  
first joint inventor

John O'Connor

Inventor's signature

Citizenship U.S.A.

Date of signature

10/1/99

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Post Office Address same as above

Full name of joint  
inventor (if any)

Steven Birken

Inventor's signature

Citizenship U.S.A.

Date of signature

10/1/99

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